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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,153	09/13/2000	Matthew A. Howard III	UIOWA-8PAD1	7887

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EXAMINER
ASSADI, KATHRYN L

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/661,153	HOWARD III, MATTHEW A.	
	Examiner	Art Unit	
	Kathryn L Assadi	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 3-7-02 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 8-15,22,23,35-38 and 40-51 is/are pending in the application.

4a) Of the above claim(s) 22,23,35-38 and 45-51 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 8-15 and 40-44 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 9-13-00 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (Claims 8-15 and 40-44) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the search and examination of the instant application could be made without serious burden in accordance with MPEP §803. This is not found persuasive because it is the Examiner's position that additional claims 22, 23, 35-38, and 45-51, drawn to a method for treating an obesity patient do indeed place a serious burden. Furthermore, the Examiner has properly met the requirement for making the restriction in accordance with MPEP § 806.05 (e).

The requirement is still deemed proper and is therefore made FINAL.

Claims 22, 23,35-38, and 45-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Examiner is unclear as to what Applicant is claiming in Claim 11. Specifically, Examiner is unsure whether Applicant is claiming at least one microinfusion catheter with many microinfusion catheters inside it, or, on the other hand, many microinfusion catheters. Examiner requests that Applicant please be clearer with the claim language of Claim 11.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Laske (US 5,720,720). Laske et al teaches a drug infusion assembly (Figure 10) for microinfusing a drug into the hypothalamus of a patient's brain comprising at least one microinfusion catheter (1) having a plurality of drug delivery ports (10), a drug delivery manifold (5), a drug supply line (4), and a drug reservoir/pump (7).

Claim Rejections - 35 USC § 103

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al in view of Corrales (US 3,941,119), further in view of Tillander (US 3,674,014). Laske et al and Corrales teach all of the claimed limitations except a macrocatheter including a magnet located at the distal end of said macrocatheter.

Tillander teaches a macrocatheter (Figure 2) including a magnet located at the distal end of said macrocatheter (4b). Tillander discloses that a magnetic field acts with the magnetic in allowing for the placement of the macrocatheter into a selected artery (Column 3, Lines14-31). It would have been obvious to one with ordinary skill in the art to use the teachings of Tillander to modify the invention of Laske and Corrales in order to create a macrocatheter with a magnetic that would allow for placement of the macrocatheter to a specific location within the patient's brain.

Claims 11 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al in view of Corrales (US 3,941,119). Laske et al teaches all of the claimed limitations except a drug infusion assembly wherein said at least one microinfusion catheter comprises a plurality of microinfusion catheters and a macrocatheter for housing the at least one microinfusion catheter. Corrales teaches a plurality of microinfusion catheters (Column 3, Line 9 and Line 27) and a macrocatheter (3) for housing the at least one microinfusion catheter (7). With regards to Claim 11, Corrales discloses that a plurality of microinfusion catheters makes it possible for selectively examining particularly sensitive portions of the body, such as when infusing substances into desired localities in the brain (Column 3, Lines 6-39). It would have been obvious to one with ordinary skill in the art to use the teachings of Corrales to modify the invention of Laske et al in order to create a drug infusion assembly wherein said at least one microinfusion catheter comprises a plurality of microinfusion catheters to deliver a drug to a separate site within the hypothalamus. With regards to Claim 40, Corrales discloses that the macrocatheter that houses the at least one microinfusion

catheter provides as a means for introducing the at least one microinfusion catheter to the part of the brain where examination takes place (Column 3, Lines 41-47). It would have been obvious to one with ordinary skill in the art to use the teachings of Corrales to modify the invention of Laske et al to create a drug infusion assembly further comprising a macrocatheter for housing the at least one microinfusion catheter and delivering the at least one microinfusion catheter to the site within the hypothalamus where the drug infusion is to take place.

Claims 12 and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al in view of Heil, Jr. (US 5,041,107). Laske et al teaches all of the claimed limitations except a 1) drug reservoir/pump that is capable of pumping a drug at a variable rate, 2) the at least one microinfusion catheter configured such that each of the plurality of drug delivery ports can be independently controlled, 3) monitoring electrodes, and 4) a controller functionally coupled to the at least one microinfusion catheter. Heil, Jr. teaches 1) drug reservoir/pump that is capable of pumping a drug at a variable rate (Column 5, Lines 39-42), 2) the at least one microinfusion catheter configured such that each of the plurality of drug delivery ports can be independently controlled (Column 3, Lines 54-55, and Column 4, Lines 13-30), 3) monitoring electrodes (22 and 26), and 4) a controller functionally coupled to the at least one microinfusion catheter (24 or 28). With regards to Claim 12, Heil, Jr. discloses that due to Faraday's Law, the drug is infused at a rate that can be precisely controlled in order to obtain a desired dose rate (Column 4, Lines 24-30). It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the

invention of Laske et al in order to create a drug reservoir/pump capable of pumping a drug at a variable rate, varying according to the amount of drug desired to be infused. With regards to Claim 42, Heil, Jr. discloses that the advantage of the delivery port being self-closing is to prevent ingress of blood or other tissue into the lumen of the microinfusion catheter. Therefore, this "self-closing" or independent closing of the drug delivery port prevents the possibility of catheter occlusion (Column 4, Lines 6-12). It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the invention of Laske et al in order to create a drug reservoir/pump wherein the at least one microinfusion catheter is configured such that each of the plurality of drug delivery ports can be independently controlled. With regards to Claim 43, Heil, Jr. discloses that the polar relationship between the electrodes and the drug, powered by the pump (12), allows for the release of the drug into the bloodstream at a specific site (Column 4, Lines 16-24). It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the invention of Laske et al in order to create a drug infusion assembly further comprising monitoring electrodes to release a drug at a desired dose rate (Column 4, Lines 25-27). With regards to Claim 44, Heil, Jr. discloses that the controller on the microinfusion catheter serves as a connection between the pump and an electrode. The pump through the presence of the controller powers the electrode. It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the invention of Laske et al in order to create a drug infusion assembly with a controller functionally coupled to the at least one microinfusion catheter.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al in view of Feingold (US 4,871,351). Laske teaches all of the claimed limitations except 1) a drug reservoir/pump capable of pumping a drug at a variable rate, the variable rate capable of being controlled percutaneously by a radio control unit, 2) a recharge valve for recharging said drug reservoir/pump with a drug, and 3) a recharge valve accessible percutaneously. Feingold teaches a drug reservoir/pump (8) capable of pumping a drug at a variable rate, and the variable rate capable of being controlled percutaneously by a radio control unit (1) (Column 5, Lines 34-58) and a recharge valve (9) accessible percutaneously (Column 4, Lines 20-21). With regards to Claim 13, Feingold discloses that the radio control unit is a means for activating the pumping mechanism of the pump (Column 8, Lines 11-20). It would have been obvious to one with ordinary skill in the art to use the teachings of Feingold to modify the invention of Laske in order to create a drug infusion assembly wherein said drug reservoir/pump pumps a drug at a variable rate that is controlled by a radio control unit as a means for pump activation. With regards to Claims 14 and 15, Feingold discloses that the recharge valve, accessible percutaneously by syringe, is a refilling port that refills the drug reservoir/pump with a drug (Column 4, Lines 20-34; Column 4, Lines 60-65).

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al in view of Sparks et al (US 4,940,588). Laske et al teaches all of the claimed limitations except an appetite-controlling drug for treating obesity. Sparks et al teaches

an appetite-controlling drug for treating obesity (Column 4, Lines 23). It would be obvious to one with ordinary skill in the art to use the teachings of Sparks et al to modify the invention of Laske et al to create a drug infusion assembly that contains a drug that is appetite controlling in order to treat obese patients.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Assadi whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

MICHAEL J. HAYES
PRIMARY EXAMINER

KLA
May 17, 2002